REMARKS

In the Office Action, the Examiner rejected claims 1-40. By the present Response, Applicants have amended claims 1, 4-6, 8, 11-13, 15-29, 31-35, and 37-40 for clarification of certain features in order to expedite allowance of the present application. These amendments do not add any new matter. Upon entry of these amendments, claims 1-40 will remain pending in the present application and are believed to be in condition for allowance. In view of the foregoing amendments and the following remarks, Applicants respectfully request reconsideration and allowance of all pending claims.

Preliminary Remarks

As a preliminary matter, the Examiner stated in the Office Action that a Request for Continued Examination (RCE) was filed subsequent to the Notice of Appeal filed on April 17, 2008. *See* Office Action, page 2. However, after reviewing the prosecution history of the present case, this statement is believed to be erroneous. To the contrary, the Notice of Appeal referenced by the Examiner was filed concurrently with a Pre-Appeal Brief Request for Review on April 17, 2008. On June 20, 2008, the Panel mailed a Decision instructing the Examiner to reopen prosecution, thereby resulting in the mailing of the instant Office Action. Thus, it should be noted that Applicants, to date, have not filed an RCE during the prosecution of the instant application.

Claim Rejections under Doctrine of Obviousness-Type Double Patenting

In the Office Action, the Examiner provisionally rejected claims 1-40 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-32 of co-pending Application No. 10/723,894 and claims 1-40 of co-pending Application No. 10/723,857. *See* Office Action, page 3. Although Applicants do not necessarily agree that claims 1-40 of the instant application are obvious over claims 1-32 of co-pending Application No. 10/723,894 or claims 1-40 of co-pending Application No. 10/723,857, Applicants may be willing to file a terminal disclaimer, if necessary, when claims in either of the referenced co-pending applications are indicated as allowable. Accordingly,

Applicants respectfully request that the Examiner hold the obviousness-type double patenting rejection in abeyance until the present or co-pending claims are indicated as allowable.

Claim Rejection Under 35 U.S.C. §112, Second Paragraph

In the Office Action, the Examiner rejected claims 5-6, 12-13, and 28-29 as being indefinite under 35 U.S.C. §112, second paragraph, for failing to particularly points out and distinctly claim the subject matter regarded as the invention. *See* Office Action, page 4. Specifically, the Examiner stated:

> 6. Claims 5-6, 12-13 and 28-29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicant claims, "...wherein each type of electrical sensor..." or "...wherein each type of non-electrical sensor..". [*sic*] However, the parent claim 1 claim language, "at least one of one or more types of electrical sensors ***or*** one or more types of non-electrical sensors" does not always provide support for the dependant claim. Therefore, there is not antecedent basis for the exclusivity of claims 5-6 and 12-13 exclusively requiring *each type of sensor.* Regarding claims 28-29, it is not clear by the claim language whether the motion of two or more organs is referring to the motion of the two or more organs set-forth by the parent claim. For the purposes of examination, the motion of two or more organs will be interpreted as referring to the two or more organs set forth in parent claim 25.
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> Office Action, page 4. (Emphasis in original).

Although Applicants do not necessary agree with the Examiner's reasons for rejecting claims 5-6, 12-13, and 28-29 under Section 112, second paragraph, Applicants have chosen to amend claims 5-6, 12-13, and 28-29 in order to address the Examiner's concerns and to advance prosecution, as discussed below.

Dependent Claims 5 and 6

Regarding claims 5 and 6, Applicants note that each of these claims depends from independent claim 1, which is presently amended to recite "acquiring a set of motion data for one or more organs using one or more sensors." (Emphasis added). Further, claim 5 is amended to recite that "the one or more sensors comprise two or more electrical sensors of the same type," and claim 6 is amended to recite that "the one or more sensors comprise at least one type of non-electrical sensor." (Emphasis added). As such, Applicants submit that the recitation "one or more sensors" of amended independent claim 1 encompasses *both* electrical and non-electrical sensors, thereby providing proper antecedent basis for "two or more electrical sensors of the same type," as recited by claim 5, and "one type of non-electrical sensor," as recited by claim 6.

Dependent Claims 12 and 13

Regarding claims 12 and 13, Applicants note that each of these claims depends from independent claim 8, which is presently amended to recite "acquiring a set of motion data for one or more organs using at least one electrical sensor and at least one non-electrical sensor." (Emphasis added). In other words, amended independent claim 8 clearly recites the use of *both* an electrical sensor and a non-electrical sensor.

With this in mind, Applicants note that claim 12 is amended to recite that "the at least one electrical sensor comprises two or more electrical sensors of the same type," and claim 13 is amended to recite that "the at least one non-electrical sensor comprises one or more types of non-electrical sensors." (Emphasis added). As such, Applicants submit that the recitation "at least one electrical sensor *and* at least one non-electrical sensor" of amended independent claim 8 provides proper antecedent basis for "two or more electrical sensors of the same type," as recited by claim 12, and "one or more types of non-electrical sensors," as recited by claim 13.

Dependent Claims 28 and 29

Dependent claims 28 and 29 depend from independent claim 25. In the Office Action, the Examiner stated that it is unclear from the language of claims 28 and 29 as to whether "activity indication of the motion of two or more organs" refers to the motion of the two or more organs recited by independent claim 25. By the present Response, claims 28 and 29 are amended to recite "activity indication of the motion of the two or more organs," thus clearly indicating that the recited motion is intended to refer to the motion of the two or more organs recited by independent claim 25.

In summary, Applicants believe that the amendments discussed above sufficiently address the Examiner's rejection of each of claims 5-6, 12-13, and 28-29 under 35 U.S.C. §112, second paragraph and, therefore, respectfully request that the Examiner withdraw the rejection of claims 5-6, 12-13, and 28-29.

Claim Rejections Under 35 U.S.C. §102

In the Office Action, the Examiner rejected claims 1-26, 31, and 37-40 under 35 U.S.C. §102(b) as being anticipated by Yuan et al., *Cardiac-Respiratory Gating Method for Magnetic Resonance Imaging of the Heart*, Magnetic Resonance in Medicine, Volume 43, Pages 314-318 (hereinafter "the Yuan reference"). Applicants respectfully traverse this rejection.

Legal Precedent

Anticipation under Section 102 can be found only if a single reference shows exactly what is claimed. *See Titanium Metals Corp. v. Banner*, 227 U.S.P.Q. 773 (Fed. Cir.1985). For a prior art reference to anticipate under Section 102, every element of the claimed invention must be identically shown in a single reference. *See In re Bond*, 15 U.S.P.Q.2d 1566 (Fed. Cir.1990). That is, the prior art reference must show the *identical invention "in as complete detail as contained in the ... claim"* to support a *prima facie* case of anticipation. *Richardson v. Suzuki Motor Co.*, 9 U.S.P.Q. 2d 1913, 1920 (Fed.

Cir. 1989) (emphasis added). Thus, for anticipation, the cited reference must not only disclose all of the recited features but must also disclose the *part-to-part relationships* between these features. *See Lindermann Maschinenfabrik GMBH v. American Hoist & Derrick*, 221 U.S.P.Q. 481, 486 (Fed. Cir.1984). Accordingly, Applicants need only point to a single element or claimed relationship not found in the cited reference to demonstrate that the cited reference fails to anticipate the claimed subject matter.

Deficiencies of the Yuan Reference

Although Applicants do not necessarily agree with the Examiner's assertions that the Yuan reference teaches *every* feature recited by independent claims 1, 8, 15, 25, 31, 37, 38, 39, and 40, Applicants have chosen to amend each of the pending independent claims for clarification of certain features. For instance, as discussed further below, independent claims 1, 15, 25, 37, and 39 are amended to recite the validation of motion data acquired via sensors using another set of motion data derived from a dataset (e.g., image data) acquired via an imager, and independent claims 8, 20, 31, 38, and 40 are amended to recite the determination of one or more motion compensation factors based upon the acquired set of motion data. These features are believed to be absent from the Yuan reference.

1. The Yuan reference fails to disclose the validation of the sensor-acquired set of motion data using another set of motion data derived from a dataset acquired via an imager.

Independent claim 1, as amended, recites a method comprising, *inter alia*, "acquiring a set of motion data for one or more organs using one or more sensors" and "validating the set of motion data using another set of motion data derived from a dataset acquired via an imager." (Emphasis added). Independent claims 15 and 37, as amended, are directed towards a computer program (e.g., computer readable media storing executable code) and an imaging system adapted to perform the method recited by independent claim 1. Independent claims 25 and 39 also recite imaging systems that

include an imager and data processing circuitry configured to validate a set of motion data obtained using one or more sensors by using another set of motion data derived from a dataset acquired via the imager.

Applicants respectfully submit that support for these claim amendments may be found at least in Figs. 2 and 4, as well as on pages 11 and 16 of the Specification. For instance, the Specification notes that a variety of processes may be used for detecting and/or measuring organ motion, including image-based detection and/or measurement (block 50 of Fig. 2), which may include acquisition data (block 60) or pre-acquisition data (block 56). *See* Specification, page 10, line 31 – page 11, line 21. Additionally, with regard to the flow chart depicted in Fig. 4, the Specification further states that motion data acquired via electrical and/or non-electrical sensors may be validated using *another set* of motion data derived or computed (either in one dimension or in two dimensions) from either unreconstructed or reconstructed acquisition image data. *See id.* at page 16, lines 1-4.

The Yuan reference generally discloses a technique for acquiring cardiac image data using magnetic resonance imaging (MRI), whereby the acquisition of the cardiac image data occurs during coinciding periods of end-expiration of a respiratory signal and QRS peaks of a cardiac signal. *See* Yuan, pages 314-315 ("Device" section). The end-expiration periods are determined using a rubber bellows (to provide a respiratory signal), and the QRS peaks are determined using an electrocardiogram (ECG). *See id.* As stated in the Yuan reference, typically two or three QRS peaks occur within a window defined by the end-expiration phase of the respiratory organ. *See id.* at page 315. However, to the extent that the Yuan reference discloses that the acquisition of cardiac image data is selective based upon organ motion (which the Examiner's appears to equate to prospective gating), there does not appear to be any indication that the motion data acquired via the bellows and ECG devices is *also* validated. For example, as shown in Fig. 1 of the Yuan reference, the respiratory and ECG signals are received by a controller

(PAC), which forwards the signals to an interface board (Tyme Card) that provides analog outputs for monitoring purposes. *See id.* at Fig. 1. The respiratory and ECG signals are then forwarded to the cardiac-respiratory gating device, which is used to control the MR imaging device. *See id.* Indeed, after careful review, Applicants are unable to identify any teaching to suggest that the asserted motion data (e.g., the respiratory and ECG signals) are validated, much less that they are validated using another set of motion data derived from a dataset acquired using an imager, as recited by each of amended independent claims 1, 15, 25, 37, and 39.

In view of these deficiencies, among others, no *prima facie* case of anticipation is believed to exist with regard to independent claims 1, 15, 25, 37, and 39 based on the Yuan reference. Accordingly, Applicants respectfully request that the Examiner withdraw the rejection under 35 U.S.C. § 102(b) of independent claims 1, 15, 25, 37, and 39, as well as their respective dependent claims.

2. *The Yuan reference fails to disclose one or more motion compensation factors.*

Independent claim 8, as amended, recites a method comprising, *inter alia*, "acquiring a set of motion data for one or more organs using at least one electrical sensor and at least one non-electrical sensor" and "processing the set of motion data to extract two or more prospective gating points for an organ of interest and to extract one or more motion compensation factors." (Emphasis added). Independent claims 20 and 38, as amended, are directed towards a computer program (e.g., computer readable media storing executable code) and an imaging system adapted to perform the method recited by independent claim 8. Independent claims 31 and 40 also recite imaging systems that include system control circuitry configured operate the imager and/or data acquisition circuitry based upon "one or more motion compensation factors derived from a set of motion data describing the motion of two or more organs within a region of interest." (Emphasis added).

Support for these claim amendments may be found at least in Fig. 4, as well as on page 16 of the Specification. For instance, with regard to the flow chart depicted in Fig. 4, the Specification discloses that once the quiescent periods 88 are identified, the quiescent periods may be used to determine one or more motion compensation factors 106. *See* Specification, page 16, line 17-27. By way of example, the determination of such motion compensation factors 106 may include modeling anticipated motion based on the multi-input motion data 72 and/or quiescent periods 88. *See id.* Additionally, the motion compensation factors 106 may be determined using a priori information about the organ of interest. *See id.*

The Yuan reference, to the contrary, does not appear to discuss or even suggest the determination or use of motion compensation factors. For instance, as discussed above, the Yuan reference discloses that a respiratory signal and a cardiac signal (ECG) are used collectively to time the acquisition of cardiac image data using an MR imaging device. *See* Yuan, pages 314-315. However, Applicants, after carefully reviewing the cited reference, are unable to locate any language teaching or suggesting that one or more motion compensation factors are derived from the motion data (e.g., the respiratory signal from the bellows and the ECG signal from the ECG), as recited by independent claims 8, 20, 31, 38, and 40.

In view of these deficiencies, among others, no *prima facie* case of anticipation is believed to exist with regard to independent claims 8, 20, 31, 38, and 40 based on the Yuan reference. Accordingly, Applicants respectfully request that the Examiner withdraw the rejection under 35 U.S.C. §102(b) of independent claims 8, 20, 31, 38, and 40, as well as their respective dependent claims.

Dependent Claims 3, 10, 17, and 22

Claims 3, 10, 17, and 22 depend from independent claims 1, 8, 15, and 20, respectively, and each generally recite fusing a set of image data representative of structure with at least one of either image data representative of motion or an image data set representative of electrical activity. By way of example, the Specification states that image data may be fused, such that motion data (either electrical or non-electrical) derived from the multi-input motion data set 72 may be combined with image data (e.g., a reconstructed structural image of an organ) to visually convey motion, acceleration, displacement, polarization, or some other sensed parameter in conjunction with structure. *See* Specification, page 18, lines 22-28.

In the Office Action, the Examiner asserted that the Yuan reference discloses fusing of image data sets. Specifically the Examiner cited to the entirety of the "Analysis" and "Discussion" sections on pages 315 and 317, respectively, of the Yuan reference. These cited passages are reproduced below:

> **Analysis**
>
> End-systolic long-axis images of the left ventricle (LV) in normal volunteers with one-dimensional SPAMM tags perpendicular to the LV long axis across the heart wall were analyzed for the comparison of the three respiratory conditions. A custom-written IDL (Interactive Data Language, Research Systems Inc., Boulder, CO) program was used to manually extract the signal intensity profile of the tags on the lateral free wall of the left ventricle. The profile was interpolated using a sinc function through zero filling of the Fourier transform of this function in the corresponding k-space. First-order baseline correction was also performed on the tag profile to compensate for the image nonuniformity due to the use of phased-array receiver coils. From the profile function, the full width at half-maximum (FWHM) of the tag and the maximum signal intensity difference between tag and myocardium (background) were then computed, which mathematically define the tag sharpness and the tag-myocardium contrast,

respectively. Statistical differences in either FWHM of the tags or tag-myocardium contrast among the three respiratory conditions across the eight volunteers were studied using a single factor analysis of variance (ANOVA) (Statview, Abacus Concepts, Inc., Berkeley, CA). A level of $p < 0.05$ was considered statistically significant. When ANOVA analysis determined that the effects of the above two variables were significantly different, multiple comparisons were performed using the Scheffe's test, which provided all possible pair-wise comparisons of means of these variables among the respiratory conditions.

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Discussion

We have demonstrated that both cardiac-respiratory gating and breath-hold methods significantly reduce respiratory motion artifacts in tagged cardiac MR images. One-dimensional tags embedded in myocardium provide us a semi-quantitative estimate of motion artifact reduction. The FWHM of the tag and the maximum signal intensity difference between tag and the myocardium were determined in order to characterize the tag sharpness as well as the tag-myocardium contrast. However, this method has its limitations. In the comparison study, three out of the eight volunteers showed no improvement of average FWHM of the tags during cardiac-respiratory gating and breath-hold compared to free breathing without respiratory gating. On the images obtained during free breathing without respiratory gating, thinner tags were observed due to fading from the motion, which might have resulted in a smaller apparent FWHM of the tags measured, despite the actual motion blurring.

In cardiac functional studies using tagging techniques, good contrast between the tags and myocardium is essential in image analysis. Breath-hold cardiac-gated fast imaging techniques improve image contrast by eliminating respiratory motion. In the cardiac-respiratory gating approach, ECG triggers were only passed through to initiate image acquisition at or near end-expiration. The increased signal intensity of myocardium due to magnetization recovery during inspiration enhanced image contrast; however, it also caused k-space modulation, which could result in image artifacts and edge

corruption. In our study, signal averaging was often used in order to increase SNR in high temporal and spatial resolution images. Over-sampling of k-space (made possible by respiratory gating) was performed to exclude aliasing artifacts in the image. The measured tag-myocardium contrast was found to be greater during cardiac-respiratory gating compared to breath-hold. No tag edge corruption was observed in cardiac-respiratory gated images.

Using the dual cardiac-respiratory gating device, MR echoes are acquired only during the expiration phase of respiration. Single image data acquisition time is prolonged 1.5-4 times compared to breath-hold data acquisition, depending on the heart rate and respiratory rate. However, additional respiration recovery time between images is needed in breath-hold studies. The total imaging time is thus approximately the same in multi-location cardiac MR studies using these two methods. Since respiratory gating does not require respiration suspension, it avoids potential changes in the heart rate and function during prolonged breath-holds, or changes in the heart location due to differing breath-holds. It also avoids data loss due to the patient's inability to cooperate with prolonged and repeated breath-holds. In patients with higher heart rate and lower respiratory rate, the efficiency of cardiac-respiratory gating improves. In our cardiac tagging study, the fast gradient echo imaging sequence (FASTCARD, GE) used was designed so that multiphase tagged cardiac images at one location could be acquired within a single breath-hold. The conventional phase encoding reordering technique is not supported with this technique. Hence, we have left the comparison of phase encoding reordering respiratory compensation techniques and our method for future study.

Using a bellows-type device to monitor respiration is easier to implement in standard clinical MRI environments compared to the navigator echo technique. It requires little software modification if an external trigger input is available. If not, the output signal from the gating device can be connected directly to an LED, which can trigger the photopulse sensor of a peripheral gating system of the scanner. Another advantage of using the external ECG trigger device is that the QRS detection circuitry can

> suppress the enlarged T-wave due to blood flow in the magnetic field, which may be further increased in response to medication such as dobutamine during MRI cardiac stress tests.
>
> Yuan, pages 315, 317.

As best understood, the Analysis section of the Yuan reference generally discusses the comparison of cardiac images obtained from multiple volunteers to identify respiratory conditions. Further, the Discussion section appears to merely summarize that the image acquisition technique disclosed by Yuan significantly reduces motion artifacts in MR imaging, but with the noted drawback of increasing image acquisition times (e.g., 1.5 to 4 times longer). However, contrary to the Examiner's assertions, Applicants, after carefully reviewing the cited passages of the Yuan reference, are unable to identify any language teaching or suggesting the fusing of image data sets, as recited by dependent claims 3, 10, 17, and 22.

For at least this reason, Applicants respectfully submit that dependent claims 3, 10, 17, and 22 are allowable not only by virtue of their dependency from claims 1, 8, 15, and 20, respectively, but also for the subject matter separately recited.

Dependent Claims 7, 14, 19, and 24

Claims 7, 14, 19, and 24 depend from independent claims 1, 8, 15, and 20, respectively, and each generally recite that a set of motion data is at least partially acquired from a set of pre-acquisition image data. For instance, the Specification, with reference to Fig. 2, states that pre-acquisition data, including navigator echoes in MRI imaging, scout images in CT imaging, and fluoroscopic images in X-ray imaging, may contribute to a set of multi-input motion data 72. *See* Specification, page 11, lines 13-21. By way of example, a navigator echo pulse (which is a quick MR pre-pulse sequence) measures the position of an organ *before* primary image acquisition. This feature is believed to be absent from the Yuan reference.

In setting forth the current rejection, the Examiner asserted that Yuan discloses the use of pre-acquisition image data in the Analysis section on page 315 (reproduced above). As mentioned above, however, the Analysis section merely discusses the comparison of image data after the application of the cardiac imaging technique was applied to obtain image data from several volunteer subjects. Contrary to the Examiner's assertions, Applicants, after carefully reviewing the cited passages of the Yuan reference, are unable to identify any language teaching or suggesting the a set of motion data is at least partially acquired from a set of pre-acquisition image data, as recited by dependent claims 7, 14, 19, and 24.

For at least this reason, Applicants respectfully submit that dependent claims 7, 14, 19, and 24 are allowable not only by virtue of their dependency from claims 1, 8, 15, and 20, respectively, but also for the subject matter separately recited.

Claim Rejections Under 35 U.S.C. §103

In the Office Action, the Examiner rejected claims 27-30 and 32-36 under 35 U.S.C. §103(a) as being unpatentable over the Yuan reference in view of Schlossbauer et al., U.S. Patent Application No. 2002/0091314 (hereinafter "the Schlossbauer reference"). Applicants respectfully traverse these rejections.

Legal Precedent

The burden of establishing a prima facie case of obviousness falls on the Examiner. *Ex parte Wolters and Kuypers*, 214 U.S.P.Q. 735 (PTO Bd. App. 1979). In addressing obviousness determinations under 35 U.S.C. §103, the Supreme Court in *KSR International Co. v. Teleflex Inc.*, 127 S. Ct. 1727 (2007), reaffirmed many of its precedents relating to obviousness including its holding in *Graham v. John Deere Co.*, 383 U.S. 1 (1966). In *KSR*, the Court also reaffirmed that "a patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art." *Id.* at 1741. In this regard, the *KSR* court stated

that "it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does … because inventions in most, if not all, instances rely upon building blocks long since uncovered, and claimed discoveries almost of necessity will be combinations of what, in some sense, is already known." *Id.* Furthermore, the *KSR* court did not diminish the requirement for objective evidence of obviousness. *Id.* ("To facilitate review, this analysis should be made explicit. See *In re Kahn*, 441 F.3d 977, 988 (CA Fed. 2006) ("[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness")). As our precedents make clear, however, the analysis need not seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ."); *see also In re Lee*, 61 U.S.P.Q.2d 1430, 1436 (Fed. Cir. 2002) (holding that the factual inquiry whether to combine references must be thorough and searching, and that it must be based on *objective evidence* of record).

Deficiencies of the Rejection

Claims 27-30 depend from independent claim 25, and claims 32-36 depend from independent claim 31. In rejecting claims 27-30 and 32-36, the Examiner acknowledged that the Yuan reference fails to teach the activation of electrical and/or electrical sensors based on the position of the sensors relative to an imager, but cited the Schlossbauer reference as allegedly curing these deficiencies. However, as discussed above, the Yuan reference fails to teach every feature recited by independent claims 25 and 31. Moreover, the Schlossbauer reference does not appear to obviate the deficiencies of the Yuan reference with regard to the missing features discussed above (e.g., the use of motion compensation factors and the validation of motion data), nor did the Examiner indicate that the Schlossbauer reference was relied upon in this regard. As such, Applicants

respectfully submit that claims 27-30 and 32-36 are allowable at least by virtue of their dependency from independent claims 25 or 31.

Conclusion

In view of the remarks and amendments set forth above, Applicants respectfully request allowance of the pending claims. If the Examiner believes that a telephonic interview will help speed this application toward issuance, the Examiner is invited to contact the undersigned at the telephone number listed below.

Respectfully submitted,

Date: December 1, 2009

/John Rariden/

John M. Rariden
Reg. No. 54,388
FLETCHER YODER
P.O. Box 692289
Houston, TX 77269-2289
(281) 970-4545